

13 Appendix: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

I. General Information.

Establishment:

Address: Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, N.J. 08830

Registration Number: 2240869

Contact Person: Mr. Jamie Yieh
Technical Specialist, Regulatory Affairs
(732) 321-4625
(732) 321-4841

Date of Summary Preparation: March 13, 2001

Device Name:

- Trade Name: MR Breast Biopsy Device
- Classification Name:
Magnetic Resonance Diagnostic Device, CFR § 892.1000
- Classification: Class II
- Performance Standards:
None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

• Device Description:

• Intended Use

The MR Breast Biopsy Device is an optional accessory to Siemens MR Systems designed to provide MR images of the breast anatomy. The Breast Biopsy Device is designed to allow access during biopsy procedure. The MR Breast Biopsy Device is compatible for use with the Siemens MAGNETOM systems, which are indicated for use as diagnostic devices that produce transverse, sagittal, coronal and oblique cross-sectional images, and that display the internal structure and/or function of the head, body, or extremities. These images when interpreted by a trained physician yield information that may assist in diagnosis.

• Technological Characteristics

MAGNETOM systems with the new MR Breast Biopsy Device is substantially equivalent to the Philips Stereotactic Localization Device (SLD).

• General Safety and Effectiveness Concerns:

Operation of MAGNETOM systems with the new MR Breast Biopsy Device is substantially equivalent to the commercially available Philips Stereotactic Localization Device (SLD). The introduction of the new Breast Biopsy Device has no significant effect on the following MR safety and performance parameters:

[Safety]

- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Level

[Performance]

- Specification Volume
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile, Thickness and Gap
- High Contrast Spatial Resolution

Siemens Medical Systems is adding an option accessory (Breast Biopsy Device) to the currently available MAGNETOM Systems. The MRI systems are exactly the same as described and cleared in the predicate premarket notifications. Therefore, the safety and performance testing was not performed as these values remain exactly as described in the 510(k)'s for these MAGNETOM systems.

- **Substantial Equivalence:**

Laboratory testing were performed to support this claim of substantial equivalence and to show that the technological differences do not raise any new questions pertaining to safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2001

Mr. Jamie Yieh
Technical Specialist, Regulatory Affairs
Siemens Medical Systems, Inc.
186 Wood Avenue South
ISELIN NJ 08830

Re: K010773
Breast Biopsy Device/Magnetom Systems
Dated: March 13, 2001
Received: March 14, 2001
Regulatory Class: II
21 CFR §892.1000/Procode: 90 LNH

Dear Mr. Yieh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known) K010773Device Name: MR Breast Biopsy Device for MAGNETOM System**Indications for Use:**

The MR Breast Biopsy Device is an optional accessory to Siemens MR Systems designed to provide MR images of the breast anatomy. The Breast Biopsy Device is designed to allow access for biopsy procedure. The MR Breast Biopsy Device is compatible for use with the Siemens MAGNETOM systems, which are indicated for use as diagnostic devices that produce transverse, sagittal, coronal and oblique cross-sectional images, and that display the internal structure and/or function of the head, body, or extremities. These images when interpreted by a trained physician yield information that may assist in diagnosis.

(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ☒ OR Over-The-Counter Use ☐

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010773